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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/885,227	06/20/2001	Moses Rodriguez	60726-A/JPW/GJG/CSN	4418

7590 04/17/2003

Cooper & Dunham LLP  
1185 Avenue of the Americas  
New York, NY 10036

EXAMINER

CHERNYSHEV, OLGA N

ART UNIT	PAPER NUMBER
1646	10

DATE MAILED: 04/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Offic Action Summary</b>	Application No.	Applicant(s)
	09/885,227	RODRIGUEZ ET AL.
	Examiner	Art Unit
	Olga N. Chernyshev	1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 06 February 2003.

2a) This action is **FINAL**.      2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-53 is/are pending in the application.

4a) Of the above claim(s) 19-53 is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1-18 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All   b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)  The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

1)  Notice of References Cited (PTO-892)

2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)

3)  Information Disclosure Statement(s) (PTO-1449) Paper No(s) Z

4)  Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_

5)  Notice of Informal Patent Application (PTO-152)

6)  Other: \_\_\_\_\_

## DETAILED ACTION

### *Election/Restrictions*

1. Applicant's election with traverse of Group I in Paper No. 9 is acknowledged. The traversal is on the ground(s) that "Groups I-III and VI are not independent of each other" (page 4, first paragraph of the Response). This is not found persuasive because an application may properly be required to be restricted to one of two or more claimed inventions if they are able to support separate patents and they are either independent (MPEP § 806.04 - § 806.04 (j)) or distinct (MPEP § 806.05 - § 806.05 (i)). The Examiner has shown that the Groups I-III and VI are independent or distinct for the reasons in the previous Office action (see Paper No. 8). Furthermore, MPEP § 803 provides that the separate classification (i.e., class and subclass) of distinct inventions is sufficient to establish a *prima facie* case that the search and examination of the plural inventions would impose a serious burden upon the Examiner; such separate classification was set forth in the Office action mailed December 03, 2002 (Paper No. 8).

The requirement is still deemed proper and is therefore made FINAL.

Claims 19-53 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 9.

Claims 1-18 are under examination in the instant office action.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

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pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-6, 8 and 11 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a monoclonal humanized antibody directed against an epitope on glatiramer acetate, does not reasonably provide enablement for any other, for example polyclonal humanized antibody directed against an epitope on glatiramer acetate. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Claims 1-6, 8 and 11 are broadly directed to a humanized antibody directed against an epitope on glatiramer acetate. It is clear from the text on pages 22-24 that the described process of how to make the claimed humanized antibody refers to a monoclonal antibody only. See, for example page 22, lines 32-33, “[t]he resulting chimeric monoclonal antibody”, emphasis added. The instant specification fails to provide any guidance or working examples on how to make any other humanized antibody except for a monoclonal antibody and there is no information known from the prior art that could lead a skilled artisan in a process of producing the claimed antibody. Therefore, in view of the lack of guidance on the subject, one skilled in the art would have to resort to a substantial amount of undue experimentation to be able to practice the full scope of Applicant's invention, as currently claimed.

3. Claims 10-18 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 10-18 are directed to a pharmaceutical composition comprising an antibody directed against an epitope on glatiramer acetate in an amount effective to treat a disease associated with demyelination of central nervous system axons. The instant specification describes the results of the experiments performed on mice infected with encephalomyelitis virus and treated by intraperitoneal injection with antibodies to glatiramer acetate. However, it is not clear and not disclosed in the instant specification what is “an amount to treat a disease associated with demyelination of central nervous system axons”. In order to extrapolate the results of improved remyelination of axons in a rodent model of experimental viral encephalitis and create a pharmaceutical composition comprising an antibody in an amount effective to treat a disease associated with demyelination of central nervous system axons, one skilled in the art would have to perform a significant amount of undue experimentation to determine the route, duration and quantity of administration of the claimed antibody to a subject. The instant specification has also failed to disclose how these parameters are to be determined, how a similar method was practiced in the art with a different agent or to provide even a single working example, prophetic or actual, of the claimed method. Because the claimed humanized antibody directed against an epitope on glatiramer acetate appears to be novel, one skilled in the art would not be able to rely on the knowledge found in the prior art for the treatment of a disease associated with demyelination of central nervous system by administration of an antibody to a substance not normally present within a body. In the absence of guidance a practitioner would have to resort to a substantial amount of undue experimentation involving the variation in the amount and duration of administration of a humanized antibody directed against an epitope on glatiramer acetate of the instant invention and in determining a suitable route of administration.

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The instant situation is directly analogous to that which was addressed in *In re Colianni*, 195 U.S.P.Q. 150,(CCPA 1977), which held that a "[d]isclosure that calls for application of "sufficient" ultrasonic energy to practice claimed method of fusing bones but does not disclose what "sufficient" dosage of ultrasonic energy might be or how those skilled in the art might select appropriate intensity, frequency, and duration, and contains no specific examples or embodiment by way of illustration of how claimed method is to be practiced does not meet requirements of 35 U.S.C. 112 first paragraph".

The standard of an enabling disclosure is not the ability to make and test if the invention worked but one of the ability to make and use with a reasonable expectation of success. A patent is granted for a completed invention, not the general suggestion of an idea and how that idea might be developed into the claimed invention. In the decision of *Genentec, Inc, v. Novo Nordisk*, 42 USPQ 2d 100,(CAFC 1997), the court held that:

"[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable" and that "[t]ossing out the mere germ of an idea does not constitute enabling disclosure". The court further stated that "when there is no disclosure of any specific starting material or of any of the conditions under which a process is to be carried out, undue experimentation is required; there is a failure to meet the enablement requirements that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art", "[i]t is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement".

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The instant specification is not enabling because one can not follow the guidance presented therein and practice the claimed invention without first making a substantial inventive contribution.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
5. Claims 1, 9 and 10 are vague and indefinite for recitation "(Copolymer 1)". It is clear that glatiramer acetate is known under different chemical and brand names. It is suggested that only one name is consistently used throughout the text of the claims.
6. Claims 2-8 and 11-18 are indefinite for being dependent from indefinite claims.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Teitelbaum et al., 1991 (reference of IDS of Paper NO. 7, page 7 ).

Claim 9 encompasses a  $F_{ab}$  fragment that binds to an epitope on glatiramer acetate. Teitelbaum et al. disclose a monoclonal antibody against the synthetic copolymer 1 (glatiramer acetate), see the abstract, for example. Teitelbaum et al. do not expressly disclose a  $F_{ab}$  fragment of their antibody.

At the time the invention was made, it would have been *prima facie* obvious to a person of ordinary skill in the art to produce a  $F_{ab}$  fragment that binds to an epitope on glatiramer acetate using a monoclonal antibody disclosed by Teitelbaum et al.. One of ordinary skill in the art would have been motivated to do this for the reason of producing antibodies for staining purposes, for example.

***Conclusion***

9. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (703) 305-1003. The examiner can normally be reached on Monday to Friday 9 AM to 5 PM ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on (703) 308-6564. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 782-9306 for regular communications and (703) 782-9307 for After Final communications.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 308-4556 or (703) 308-4242. If either of these numbers is out of service, please call the Group receptionist for an alternative number. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. Official papers should NOT be faxed to (703) 308-0294.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Olga N. Chernyshev, Ph.D. *OC*

April 16, 2003